

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) **[[A]] An *in vivo* method of reducing the size of a tumor in a mammal comprising treating** mammalian cancer cells deficient in functional p53, said method comprising **directly** contacting said cancer cells with an adenoviral vector comprising a nucleic acid encoding p53 and also contacting said cells with a microtubule affecting agent, such that growth of said cancer cells is reduced or said cancer cells undergo apoptosis, or both, wherein the mammalian cancer cells are human head and neck, ovarian, prostate, or mammary cancer cells;

wherein the microtubule affecting agent comprises a taxane.

2. (Canceled)

3. (Previously presented) The method of claim 1 wherein said microtubule affecting agent is paclitaxel or a paclitaxel derivative.

4. (Previously Presented) The method of claim 1, wherein said method further comprises contacting the cells with a chemotherapeutic agent.

5. (Original) The method of claim 4, wherein said chemotherapeutic agent is cisplatin, carboplatin, or navelbine.

6-9. (Canceled)

10. (Original) The method of claim 1, wherein said nucleic acid is delivered by a recombinant adenoviral vector.

11. (Original) The method of claim 10, wherein said nucleic acid is delivered by a recombinant adenoviral vector comprising a partial or total deletion of a protein IX DNA and comprising a nucleic acid encoding a wild-type p53 protein.

12. (Original) The method of claim 11, wherein said deletion of the protein IX gene sequence extends from about 3500 bp from the 5' viral termini to about 4000 bp from the 5' viral termini.

13. (Original) The method of claim 12, further comprising deletion of a non-essential DNA sequence in adenovirus early region 3.

14. (Original) The method of claim 11, further comprising deletion of a non-essential DNA sequence in adenovirus early region 4.

15. (Original) The method of claim 11, further comprising a deletion of DNA sequence designated E1a and E1b.

16. (Original) The method of claim 10, wherein said recombinant adenoviral vector comprises the adenovirus type 2 major late promoter or the human CMV promoter, the adenovirus type 2 tripartite leader cDNA and a human p53 cDNA.

17. (Original) The method of claim 16, wherein said vector is A/C/N/53.

18. (Previously Presented) The method of claim 1, wherein said microtubule affecting agent is selected from the group consisting of paclitaxel and docetaxel.

19. (Previously Presented) The method of claim 18, wherein said microtubule affecting agent is paclitaxel.

20. (Currently Amended) The method of claim 3, wherein said cells are first contacted with said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53 and are subsequently contacted with said paclitaxel or paclitaxel derivative.

21. (Currently Amended) The method of claim 3, wherein said cells are first contacted with said paclitaxel or paclitaxel derivative and are subsequently contacted with said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53.

22. (Currently Amended) The method of claim 3, wherein said cells are simultaneously contacted with said paclitaxel or paclitaxel derivative and with said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53.

23-24. (Canceled)

25. (Currently Amended) The method of claim 1, wherein said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53 is dispersed in a pharmacologically acceptable excipient.

26. (Previously presented) The method of claim 3, wherein said paclitaxel or paclitaxel derivative is dispersed in a pharmacologically acceptable excipient.

27. (Currently Amended) The method of claim 3, wherein said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53 and said paclitaxel or paclitaxel derivative are dispersed in a single composition.

28. (Currently Amended) The method of claim 1, wherein said contacting comprises injecting said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53 into a tumor.

29. (Canceled) ~~The method of claim 1, wherein said contacting comprises intra-arterial injection of said p53 tumor suppressor protein or nucleic acid encoding p53.~~

30. (Currently Amended) The method of claim 1 ~~[[29]]~~, wherein said contacting comprises intraperitoneal administration of said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53 for the treatment of ovarian cancer.

31. (Original) The method of claim 3, wherein said contacting comprises injecting said paclitaxel or paclitaxel derivative into a tumor.

32. (Original) The method of claim 3, wherein said contacting comprises intravenously injecting said paclitaxel or paclitaxel derivative.

33. (Original) The method of claim 1, wherein said contacting comprises systemic, regional, local, topical, intraperitoneal, intra-pleural cavity, oral, buccal, sublingual, intra-tracheal, transmucosal, bladder, vaginal, uterine, rectal, or nasal administration.

34. (Previously presented) The method of claim 3, comprising contacting said cells with A/C/N/53 and paclitaxel.

35. (Currently Amended) The method of claim 1, wherein said contacting cells with a ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53 comprises contacting said cells with said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53 in a multiplicity of treatments each separated by at least about 6 hours.

36. (Original) The method of claim 1, wherein said method comprises at least three treatments separated by about 24 hours.

37. (Currently Amended) ~~The method of claim 3, wherein:~~ An *in vivo* method of reducing the size of a tumor in a mammal comprising mammalian cancer cells deficient in functional p53, said method comprising directly contacting said cancer cells with an adenoviral vector comprising a nucleic acid encoding p53 and also contacting said cells with a taxane, such that growth of said cancer cells is reduced or said cancer cells undergo apoptosis, or both, wherein the mammalian cancer cells are human head and neck, ovarian, prostate, or mammary cancer cells;

said ~~p53 tumor suppressor protein or~~ adenoviral vector comprising a nucleic acid encoding p53 is administered in a total dose ranging from about 1×10^9 to about 7.5×10^{15}

adenovirus particles in a treatment regimen selected from the group consisting of: the total dose in a single dose, the total dose divided over 5 days and administered daily, the total dose divided over 15 days and administered daily, and the total dose divided over 30 days and administered daily; and

said paclitaxel or paclitaxel derivative is administered in a total dose ranging from about 75 to about 350 mg/m² over 24 hours in a treatment regimen selected from the group consisting of administration in a single dose, in a dose administered daily on day 1 and day 2, in a dose administered daily on day 1, day 2, and day 3, on a daily dosage for 15 days, on a daily dosage for 30 days, on daily continuous infusion for 15 days, on daily continuous infusion for 30 days.

38. (Original) The method of claim 37, wherein said method is repeated for two or more cycles.

39. (Original) The method of claim 38, wherein said two or more cycles are spaced apart by three or four weeks.

40. (Original) The method of claim 38, wherein said method is repeated for three cycles.

41-77. (Canceled)

78. (Currently Amended) [[A]] An *in vivo* method of treating human head and neck, ovarian, prostate, or mammary cancer cells in a mammal, the method comprising administering a DNA vector comprising a nucleic acid sequence encoding a p53 tumor suppressor protein directly at the cancer cells and also contacting the cells with a taxane, such that growth of said cancer cells is reduced or said cancer cells undergo apoptosis, or both; wherein the cancer cells are deficient in functional p53.

79. (Previously Presented) A method of inhibiting cell proliferation in human head and neck, ovarian, prostate, or mammary cancer cells *in vitro*, the method comprising

contacting the cancer cells with a p53 tumor suppressor protein or nucleic acid sequence encoding a p53 tumor suppressor protein and also contacting the cells with a taxane.

80. (Currently Amended) **[[A]]** An *in vivo* method of treating mammalian cancer cells deficient in functional p53, said method comprising directly contacting a sample of cells from the cancer cells with an adenoviral vector comprising a nucleic acid encoding p53 and also contacting the sample of cells with a taxane, such that one or more disease characteristic of the cancer cells is ameliorated, wherein the mammalian cancer cells are human head and neck, ovarian, prostate, or mammary cancer cells.